

**REMARKS**

Claims 1-8, 11-34, and 37, and new claims 40-42 are pending in this application. Applicants request reconsideration and allowance of these claims in light of the amendments to claims 1, 2, 8, and 37.

**Rejection under 35 U.S.C. § 102**

On pages 2 and 3 of the Office Action, the Office rejected claims 1-8, 11-14, 16-21, 25, 27, 31-32, and 34 as being anticipated by WO 98/31346, because it asserted that this reference discloses polymeric microparticles for inhalation that are coated with surfactant, contain a variety of active principles, have a density of less than  $0.4 \text{ g/cm}^3$ , and a mean diameter of 5-30  $\mu\text{m}$ . As amended, though, the claimed method provides a biocompatible microparticle with several characteristics, including:

- an apparent density between  $0.02 \text{ g/cm}^3$  and  $0.8 \text{ g/cm}^3$ ,
- an active principle/coating agent mass ratio of between 95/5 and 80/20,
- a mean diameter of between 1 and 15  $\mu\text{m}$ , and
- an external layer comprising a residual quantity of organic solvent of less than 500 ppm when an organic solvent is added to supercritical fluid.

The term “an apparent density between  $0.02 \text{ g/cm}^3$  and  $0.8 \text{ g/cm}^3$ ” appeared in the claims before amendment. Similarly, the term “a mean diameter of between 1 and 15  $\mu\text{m}$ ” appeared in claim 2 as originally filed. The claim term “an active principle/coating agent mass ratio of between 95/5 and 80/20” is supported on page 13, line 35, to page 14, line 2, of the specification. Finally, claim term “an external layer comprising a residual quantity of organic solvent of less than 500 ppm when an organic solvent is added to supercritical fluid” is supported on page 8, lines 5-8. Thus, the

addition of these terms does not add new matter. Furthermore, the elements of the new claims are supporting in the specification, for example "wherein the external layer is free of organic solvent," is supported on page 8, lines 5-8, and "wherein the optional organic solvent is ethyl acetate," is supported in Example 1, on page 16. Thus, the new claims do not add new matter.

The microparticles disclosed by WO 98/31346 do not demonstrate the characteristics of the pending claims. For example, WO 98/31346 discloses microparticles with a mean diameter "at least about 5  $\mu\text{m}$ , for example between about 5 and 30  $\mu\text{m}$ ." WO 98/31346 at p. 17, lines 27-29, but not a mean diameter of between 1 and 15  $\mu\text{m}$ . In addition, WO 98/31346 does not specify an active principle/coating agent mass ratio for the microparticles. Because the claimed method requires microparticles with a mean diameter of between 1 and 15  $\mu\text{m}$  and an active principle/coating agent mass ratio of between 95/5 and 80/20, WO 98/31346 cannot anticipate the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

Rejections under 35 U.S.C. § 103

The Office rejected claims 1-8, 11-34, and 37 under 35 U.S.C. § 103 as being obvious in view of EP 0706821 or FR 2753639, either alone or in combination with WO 98/31346 or WO 96/29998. The Office asserted that EP 0706821 discloses polymeric microparticles containing an active principle and having a mean diameter of 20 nm to 100  $\mu\text{m}$  and an apparent density between 0.02 g/cm<sup>3</sup> and 0.8 g/cm<sup>3</sup>. EP 0706821 does not specify a mean diameter of 1 to 15  $\mu\text{m}$ , though. Nor does it disclose microparticles with an active principle/coating agent mass ratio of between 95/5 and 80/20 or an

external layer comprising a residual quantity of organic solvent of less than 500 ppm, when an organic solvent is added to supercritical fluid. Furthermore, EP 0706821 does not provide any motivation for one of skill in the art to modify the microparticles disclosed to have these characteristics. Thus, EP 0706821 does not render the claimed invention obvious.

The Office also asserted that FR 2753639, as evidenced by the apparent English translation in U.S. Patent No. 6,183,783, renders the claimed invention obvious because it discloses microparticles with a diameter of 20 nm to 500  $\mu\text{m}$  with an apparent density of between 0.02  $\text{g}/\text{cm}^3$  to 0.8  $\text{g}/\text{cm}^3$  and active agents including peptides. FR 2753639, as U.S. Patent No. 6,183,783, though does not specify a microparticle with a mean diameter of between 1 and 15  $\mu\text{m}$ , because the disclosed range of 20 nm to 500  $\mu\text{m}$  does not specifically identify the narrower range. Although the specification of U.S. Patent No. 6,183,783 provides for some narrower range of microparticle size, for example claim 18 provides for a particle size of between 20 nm and 50  $\mu\text{m}$ , this range is still much broader than the claimed range of between 1 and 15  $\mu\text{m}$  and would provide no motivation for one of skill in the art to choose the claimed range. In addition, FR 2753639 does not disclose an active principle/coating agent mass ratio of between 95/5 and 80/20, nor any active principle/coating agent mass ratio. Thus, FR 2753639 does not render the claimed invention obvious.

As discussed above in the response to the rejection under 35 U.S.C. § 102, WO 98/31346 does not cure any of the defects of either EP 0706821 or FR 2753639. WO 98/31346 discloses microparticles with a mean diameter "at least about 5  $\mu\text{m}$ , for example between about 5 and 30  $\mu\text{m}$ ," but not between 1 and 15  $\mu\text{m}$ . Neither does WO

98/31346 specify an active principle/coating agent mass ratio of between 95/5 and 80/20. Thus, the combination of neither EP 0706821 nor FR 2753639 with WO 98/31346 renders the claimed invention obvious.

Finally, WO 96/29998 does not cure the defects of EP 0706821 or FR 2753639 either. WO 96/29998 discloses microparticles with a diameter of between 0.1 and 1  $\mu\text{m}$ , but this range does not encompass the claimed range of between 1 and 15  $\mu\text{m}$ . In addition, WO 96/29998 does not disclose any range of an active principle/coating agent mass ratio, and not a range of between 95/5 and 80/20. Thus, the combination of neither EP 0706821 nor FR 2753639 with WO 96/29998 renders the claimed invention obvious.

Because none of these references or combination of references renders the claimed invention obvious, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

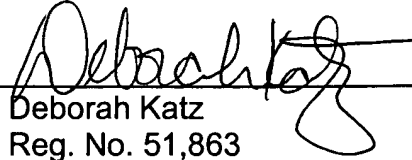
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 8, 2005

By: \_\_\_\_\_

A handwritten signature in black ink, appearing to read "Deborah Katz", written over a horizontal line.

Deborah Katz

Reg. No. 51,863

Phone: 202.408.4382

Fax: 202.408.4400

E-mail: [deborah.katz@finnegan.com](mailto:deborah.katz@finnegan.com)